

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

MDL 1456

Master File No. 01-CV-12257-PBS

THIS DOCUMENTS RELATES TO:
ALL ACTIONS

Judge Patti B. Saris

**REPLY IN SUPPORT OF IMMUNEX CORPORATION'S
MOTION TO DISMISS THE AMENDED MASTER CONSOLIDATED
CLASS ACTION COMPLAINT**

INTRODUCTION

Despite the Court's admonition that "[w]e're going to go drug by drug," Tr. of Oral Argument at 74 (Jan. 13, 2003), plaintiffs' memorandum refers largely to generalized allegations against Immunex that do not pertain to specific drugs. Plaintiffs contend that the limited "specific allegations as to Immunex and the *logical inferences to be drawn as to other drugs*" are sufficient to survive the motion to dismiss. Plaintiffs' Separate Memo. in Opp. to Def.-Specific Memoranda at 59 ("Pls. Def.-Spec. Mem.") (emphasis added). Under the doctrine of standing, the requirements of Rule 9(b), and the unique reimbursement system for multiple-source drugs, plaintiffs are wrong.

The Court should dismiss all claims against Immunex with prejudice.

I. Plaintiffs Lack Standing to Sue Immunex, Particularly as to the Immunex Drugs That No Plaintiff Purchased.

Plaintiffs' position that they have standing to sue every pharmaceutical company defendant on claims relating to *every drug* sold by that company and mentioned in the AMCC, as long as one of the named plaintiffs purchased one of that company's drugs, is squarely at odds with the Court's prior rulings in this case. The Court previously ruled that plaintiffs must identify "the name of the specific plaintiff(s) that purchased the drug," *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003), and the Court limited discovery to those drugs where "the MCC identified a specific plaintiff who purchased the drug." Case Management Order No. 7 at 2 (Aug. 15, 2003). Only two of the eleven plaintiffs purchased an Immunex drug. Pls. Def.-Spec. Mem. at 58. None of the

plaintiffs purchased Leukine® or Novantrone®. *See* App. B to AMCC.¹ The Court should dismiss all claims relating to these drugs and all claims against Immunex relating to the nine plaintiffs who failed to allege a purchase of any Immunex drug.²

II. Plaintiffs' Allegations Against Immunex Fail for Lack of the Particularity Required by Rule 9(b).

Plaintiffs misconstrue Immunex's Rule 9(b) argument by stating that Immunex argued that plaintiffs "must establish facts" to meet 9(b). Pls. Def.-Spec. Mem. at 58. In fact, Immunex argued that plaintiffs must *allege* facts against Immunex as to each drug. As the Court instructed, "You've got to meet 9(b) requirements. You've got to particularize exactly what drugs, exactly what the fraud is" Tr. of Oral Argument at 74 (Jan. 13, 2003). The "Immunex allegations" in plaintiffs' opposition contain almost no allegations about specific Immunex drugs, but only the following conclusory allegations that do not satisfy Rule 9(b):

- Immunex has been investigated, but not charged, much less convicted, by government entities regarding AWP. Pls. Def.-Spec. Mem. at 57.
- "Hoffman [sic] has stated fraudulent AWPs for all or almost all of its drugs," *id.*, and Appendix B to the AMCC lists certain published AWPs from 1997 to 2002 for five Immunex drugs, with no explanation of *how* these AWPs were fraudulent.
- A letter from Red Book to Immunex refers to "your latest AWP price changes," *id.* at 58; the letter predates the allegedly fraudulent AWPs in the AMCC.

¹ Oddly, the MCC (§ 24) alleged that Teamsters Health & Welfare Fund of Philadelphia and Vicinity ("THWF") purchased Novantrone® and thus, the only Immunex drug subject to discovery under CMO 7 is Novantrone®, even though the AMCC is deficient in failing to allege a plaintiff purchaser of this drug.

² The only plaintiffs who purchased an Immunex drug are United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund (methotrexate sodium and Thioplex®) and THWF (leucovorin calcium and methotrexate sodium). App. B to AMCC. Plaintiffs ignore Immunex's argument that they lack standing to sue Immunex because they did not allege the actual prices they paid for these drugs.

- Immunex set up a "Reimbursement Hotline" for a number of its products" and "provid[ed] free samples," *id.*; there are no specifics as to which products were allegedly sampled or how that was fraudulent.
- A government report noted that the AWP for Immunex's leucovorin calcium and methotrexate sodium "were substantially higher than the actual prices listed by wholesalers,"³ *id.*; there is no similar allegation regarding AWP for Immunex's single-source drugs, and no explanation of when "higher" becomes fraudulent.
- Novantrone® pricing "resulted in a 21.36% spread" in 1997, *id.*; there are no allegations about any other year, nor a response to Immunex's argument that plaintiffs failed to explain how a spread in that amount was fraudulent.

Plaintiffs also fail to point to any specific "spread" allegations in the AMCC for Leukine® or Thioplex®. The information necessary to make a specific allegation of a fraudulent spread is in plaintiffs' possession: plaintiffs know what they paid for the drugs they allegedly purchased and, as to Immunex, plaintiffs concede that they possess information about actual prices from the boxes and boxes of documents that Immunex produced regarding all five drugs at issue. *See* AMCC ¶ 433.

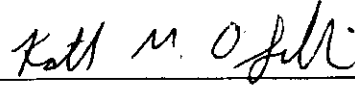
III. The Court Should Dismiss All Claims About Multi-Source Drugs.

As outlined in the defendants' joint reply, the Court should again dismiss all claims relating to multiple-source drugs, including leucovorin calcium and methotrexate sodium.

³ The AMCC fails to mention the report's conclusion: DHHS recommended that published AWP continue to serve as the basis for reimbursement for leucovorin calcium, methotrexate sodium, and certain other cancer drugs because the agency had "some concern about access to care related to the DOJ's wholesale prices for [these drugs], due to other Medicare payment policies associated with the provision of these drugs." Department of Health & Human Servs., Health Care Financing Admin., *An Additional Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program*, PM Rev. AB-00-86 (Sept. 8, 2000), available at <http://www.irpsys.com/refinfo/hcfapm/AB-00-86.htm>.

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